Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: October 3, 2007
HRT Laboratory, Inc.,	
Petitioner,	Civil Remedies CR1497
	App. Div. Docket No. A-07-22
- v. -	Decision No. 2118
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

HRT Laboratory, Inc. (Petitioner) appeals the August 31, 2006 decision of Administrative Law Judge (ALJ) Carolyn Cozad Hughes. HRT Laboratory, Inc., DAB CR1497 (2006) (ALJ Decision). The ALJ dismissed Petitioner's request for a hearing on a determination of the Centers for Medicare & Medicaid Services (CMS) revoking Petitioner's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a et seq., cancelling Petitioner's approval to receive Medicare payments, and imposing a civil money penalty (CMP). The ALJ dismissed the hearing request on the ground that Petitioner did not dispute that it was not in substantial compliance with CLIA requirements and challenged only the rejection of its proposed plan of correction, an action that the ALJ determined is not appealable under the CLIA regulations.

As explained below, we sustain the ALJ Decision.[1]

[1] Our decision is based on the parties' written submissions and the ALJ record. With its request for review, (continued...)

Applicable law and regulations

Part 493 of 42 C.F.R. "sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under [CLIA]." 42 C.F.R. § 493.1. With the limited exceptions specified in 42 C.F.R. § 493.3(b), a laboratory performing such tests is not in compliance with CLIA requirements unless it has one of the certificates specified in the regulations or is CLIA exempt. 42 C.F.R. §§ 493.3, 493.5(c). Tests are categorized by complexity, and there are CLIA certification conditions (or requirements for "waived tests") specific to each category. See 42 C.F.R. §§ 493.5, 493.20, 493.25 and the subparts cited therein. Each certification condition represents a general requirement that must be met, and CLIA standards are the specific components of the conditions. 42 C.F.R. Part 493; see Edison Medical Laboratories, DAB No. 1713, at 2 (1999), aff'd, Edison Medical Lab. v. Thompson, 250 F.3d 735 (3rd Cir. 2001).

A laboratory's failure to comply with even a single applicable condition is a ground for CMS to impose one or more principal or alternative sanctions. 42 C.F.R. § 493.1806(a). Principal sanctions that CMS may impose include suspension, limitation, or revocation of a laboratory's CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions that CMS may impose include a directed plan of correction, State onsite monitoring, and/or a civil money penalty (CMP). 42 C.F.R. § 493.1806(c).

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[1](...continued)
Petitioner submitted additional exhibits A through N. Apart from two letters from the California Department of Health Services (Petitioner Exhibits I and J), these exhibits consist of documents that the ALJ previously admitted to the record and correspondence from the Civil Remedies Division to Petitioner enclosing the ALJ Decision. ALJ Decision at 3. The Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing if the Board considers that the additional evidence is relevant and material to an issue before it. 42 C.F.R. § 498.86(a). The Board's guidelines also provide that the Board will consider whether the proponent demonstrates good cause for not having produced the evidence before the ALJ. Board Guidelines – Appellate Review of Decisions of Administrative Law Judges in Cases under CLIA and Related Statutes, http://www.hhs.gov/dab/guidelines/clia.html. Petitioner did not show how its Exhibits I and J are relevant and material or explain why they were not produced during proceedings before the ALJ. Accordingly, we do not admit them to the record.

Additionally, if a laboratory that has approval to receive Medicare payment for its services is out of compliance with one or more CLIA conditions, CMS may cancel the laboratory's approval to receive Medicare payment for its services. 42 C.F.R. § 493.1806(a). For a condition-level deficiency that does not pose immediate jeopardy, the range of the penalty CMS may impose is $50-$3,000 per day of noncompliance or per violation. 42 C.F.R. § 493.1834(d)(2)(ii). A laboratory issued a CLIA certificate must permit CMS or its agent to conduct an inspection to assess the laboratory's compliance with CLIA regulations at 42 C.F.R. Part 493. 42 C.F.R. §§ 493.1771, 493.1773. Additionally, each certified laboratory performing non-waived tests must successfully participate in a proficiency testing program approved by HHS, which evaluates the laboratory's analyses of test samples distributed to participating laboratories. 42 C.F.R. Part 493, Subparts H, I.

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA sanctions and may request review of the ALJ's decision by the Departmental Appeals Board. 42 C.F.R. § 493.1844(a). The CLIA regulations state that the following actions are "initial determinations" and, therefore, subject to appeal:

> (1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by CMS because of noncompliance with CLIA requirements.
> (2) The denial of a CLIA certificate.
> (3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).
> (4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

42 C.F.R. § 493.1844(b). Actions not listed above are not "initial determinations" and, therefore, are not subject to appeal under the CLIA appeal regulations. 42 C.F.R. § 493.1844(c). The regulations also specify that CMS's determinations as to which alternative sanctions to impose, the amount of any CMP and that a laboratory's deficiencies pose immediate jeopardy are not "initial determinations" and, therefore, are not appealable. 42 C.F.R. § 493.1844(c).

The CLIA regulations incorporate by reference the hearing procedures and review provisions in 42 C.F.R. Part 498, subparts D and E. 42 C.F.R. § 493.1844(a). The request for hearing must–

> (1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and
>
> (2) Specify the basis for contending that the findings and conclusions are incorrect.

42 C.F.R. § 498.40(b).

Background

Petitioner was a California clinical laboratory certified under CLIA. The California Department of Health Services, Laboratory Field Services (State Agency), informed Petitioner, in a letter dated June 20, 2005, that based on a recertification survey conducted during the period January 28 through March 8, 2005, Petitioner was out of compliance with various standard-level requirements and the following four CLIA conditions: 42 C.F.R. §§ 493.803 (successful participation in proficiency testing); 493.1230 (general laboratory systems); 493.1250 (analytic systems); and 493.1403 (laboratory director – moderate complexity testing). CMS Exhibit (Ex.) 9. The letter instructed Petitioner to submit, within ten days, a credible allegation of compliance and acceptable evidence of correction, and warned that, if Petitioner failed to correct its deficiencies, the State Agency would recommend that CMS impose sanctions, including revocation of Petitioner's CLIA certificate. Id. The State Agency enclosed with the letter a Form CMS-2567 containing a statement of the deficiencies found during the survey and instructed Petitioner to document its credible allegations of compliance on the Form 2567 in the columns headed "Provider Plan of Correction" and "Completion Date."[2] Id. at 1, 2.

[2] Since the State Agency asked Petitioner to document the "credible allegation of compliance" on the part of the CMS Form 2567 used for a "Plan of Correction" or "POC" and the parties sometimes referred to Petitioner's submissions in response as POCs, we use the terms "credible allegation of compliance" and "POC" interchangeably for purposes of this decision. However, we note the detailed instructions the letters gave Petitioner as to what an allegation of compliance must contain in order to be "credible," including that it "[i]ndicates resolution of the problems." CMS Ex. 9, at 1-5. We also note the detailed instructions as to what would constitute acceptable evidence documenting correction. Id. Petitioner has not argued that it was somehow confused about what it had to submit in order to make a "credible allegation of compliance" or to show

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On or about July 8, 2005, Petitioner submitted a POC to the State Agency. P. Hearing Exs. A, 3. In a letter dated August 12, 2005, the State Agency informed Petitioner that the plan was unacceptable, enclosed a statement of reasons, and told Petitioner to submit another allegation of compliance and evidence of correction within 10 days after receipt of the letter. CMS Ex. 9, at 4. The letter warned that the State Agency would recommend sanctions to CMS if Petitioner failed to submit a credible allegation of compliance and acceptable evidence of correction or if it was found to be still out of compliance with any CLIA condition-level requirements. Id. at 4-5. On or about September 1, 2005, Petitioner submitted a second POC. P. Hearing Exs. A, 6. In a letter dated October 5, 2005, the State Agency informed Petitioner that its second allegation of compliance was not credible and the evidence submitted was not acceptable, and that the State Agency was recommending that CMS impose sanctions. CMS Ex. 9, at 9-10.

CMS adopted the State Agency's recommendations. In a letter to Petitioner dated November 3, 2005, CMS stated that it concurred with the State Agency's findings and recommendations, explained why Petitioner's second allegation of compliance was not credible and its evidence of correction was not acceptable, and proposed the principal sanctions of revocation of Petitioner's CLIA certificate and cancellation of its approval to receive Medicare payments, and the alternative sanction of a CMP of $3,000 per day effective November 18, 2005. CMS Ex. 10. CMS also proposed a directed portion of a POC by which Petitioner was to submit a list of names and addresses of all physicians, providers, suppliers and other clients who had used the laboratory's services since July 2002.[3] Id. at 13; see 42 C.F.R. § 493.1832(b)(2) (providing for directed portions of plans of correction to enable CMS, via the State Agency, to notify clients of a sanctioned laboratory because of the seriousness of the

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[2](...continued)
"evidence of correction." Neither does Petitioner argue that its submissions show it actually achieved compliance. Instead, Petitioner argues that the POC prepared by its technical consultant and submitted on September 1, 2005 "would have brought" the laboratory into compliance in the future. P. Request for Review (RR.) at 8.

[3] We note that a "Directed Plan of Correction" or "Directed Portion of a Plan of Correction" are alternative sanctions, and thus different from a "POC." See 42 C.F.R. §§ 493.1806(c)(1), 493.1832.

noncompliance).[4] CMS gave Petitioner until November 13, 2005 to submit in writing any evidence or information as to why those sanctions should not be imposed. Id. at 14. In a letter dated November 14, 2005, Petitioner informed CMS that it had ceased doing business and had stopped testing as of November 2, 2005. CMS Ex. 13. CMS thereafter informed Petitioner, in a letter dated November 16, 2005, that CMS was imposing the recommended sanctions and that Petitioner could appeal CMS's determination in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R. Part 498 by submitting within 60 days a written request for hearing that –

> must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect.

CMS Ex. 11. In a letter dated November 22, 2005, Petitioner stated that it "formally appeal[ed] the proposed sanctions and any and all actions proposed by [the Department of Health and Human Services] in your letters dated November 3, 2005, and November 16, 2005, and any other proposed sanctions which may have been imposed or recommended." ALJ Decision at 3, citing P. Hearing Request (November 22, 2005). CMS moved to dismiss, or, in the alternative, for summary judgment, and Petitioner filed a brief in opposition.

The ALJ Decision

The ALJ made the following findings of fact and conclusions of law:

> 1. Petitioner has not appealed CMS's determination that the lab failed to meet federal conditions of certification – 42

[4] In an October 19, 2006 letter, CMS informed Petitioner that the CMP of $3,000 per day would accrue from November 18, 2005 through December 23, 2005, the date CMS received Petitioner's list of clients under the directed portion of a POC, instead of through August 30, 2006, the date of the ALJ Decision. CMS Ex. A. CMS submitted the exhibit with its appeal brief, and Petitioner has not objected to it. Absent any objection, we admit CMS Exhibit A to the record solely to show that CMS modified the end date of the CMP (to shorten its duration) after the ALJ Decision.

> C.F.R. §§ 493.803, 493.1230, 493.1250, and 493.1403 – and those determinations are therefore final and binding.
>
> 2. Because the lab was out of compliance with one or more conditions, CMS is authorized to impose sanctions.
>
> 3. CMS's rejection of Petitioner's plan of correction is not an "initial determination" reviewable in this forum.

ALJ Decision at 3, 5. The ALJ found that Petitioner's hearing request "provides no clue as to the issues or findings challenged or the bases for that challenge" and "simply challenges the sanctions and 'all of the actions proposed'" despite the regulatory requirements for a hearing request at 42 C.F.R. § 498.40(b) and the "unambiguous language" in CMS's determination letter informing Petitioner of what its request for hearing must contain. ALJ Decision at 4.

The ALJ further found that Petitioner's brief opposing CMS's motion did not challenge CMS's determination that Petitioner was not in substantial compliance with four conditions of certification and instead "contests only CMS's rejection of its plan of correction, arguing that its submissions were 'comprehensive and appropriate, and would have brought [it] into compliance.'" Id., citing P. Brief (Br.) at 6. The ALJ concluded that Petitioner thus did not dispute that it was not in substantial compliance with four conditions of certification, and that, because Petitioner had not contested CMS's noncompliance determinations, they were final and binding. ALJ Decision at 4, citing 42 C.F.R. § 498.20(b) (providing that an initial determination is binding unless reversed or modified by a hearing decision, or under other circumstances not applicable here). Id. Because Petitioner had at least one condition-level deficiency, the ALJ concluded, CMS had authority as a matter of law to revoke its CLIA certificate and impose alternative sanctions. Id. at 5, citing 42 C.F.R. §§ 493.1806, 493.1804(b).

The ALJ further concluded that the "sole issue" that Petitioner raised – the rejection of Petitioner's POC – was not one of the "initial determinations" specified in 42 C.F.R. § 493.1844(b) that may be appealed. Id. at 5. She also noted that "CMS's choice of alternative sanctions, including the amount of a CMP, is not an initial determination reviewable in this forum." Id., citing 42 C.F.R. § 493.1844(c)(4).

Standard of Review

The standard of review on factual issues is whether the ALJ decision is supported by substantial evidence in the whole record. The standard of review on issues of law is whether the ALJ decision is erroneous. See Guidelines; U.S. Bio-Chem Medical Laboratories, Inc., DAB No. 1731 (2000).

Petitioner's arguments

On appeal, Petitioner does not dispute CMS's determination that Petitioner had four condition-level CLIA deficiencies at the time of the State Agency's survey. Petitioner also does not dispute the ALJ's finding that Petitioner did not challenge that determination, despite the clear instructions, in the regulations and in CMS's letter imposing sanctions, that Petitioner identify the specific issues and the findings of fact and conclusions of law with which it disagreed, and state the basis for contending that those issues, findings and conclusions were incorrect. ALJ Decision at 4. Nor does Petitioner dispute that the rejection of a POC is not listed as an appealable "initial determination" at 42 C.F.R. § 493.1844(b).

Petitioner argues nonetheless that the ALJ erred in determining that the rejection of Petitioner's POC was not an "initial determination" under 42 C.F.R. § 493.1844 and was thus not subject to review by the ALJ. Petitioner argues that the rejection of its POC was an appealable initial determination because it was the basis for CMS's decision to revoke Petitioner's CLIA certificate and cancel its approval to receive Medicare payments, which Petitioner argues was inextricably linked with the rejection of its POC. P. Reply at 2. As support, Petitioner cites language in the State Agency's letters first warning that Petitioner's failure to submit a credible allegation of compliance and acceptable evidence of correction or to demonstrate compliance with CLIA requirements could result in CMS imposing those sanctions, and later informing Petitioner that the State Agency was recommending that CMS impose sanctions. Petitioner also cites CMS's subsequent decision to adopt the State Agency's findings and impose the sanctions Petitioner now challenges. P. Exs. 2, 8; CMS Exs. 9, 11.

Petitioner additionally argues that dismissal of its hearing request was not appropriate because the declaration of an expert it retained to prepare its September POC raised a genuine issue of fact as to whether the POC would have demonstrated compliance with CLIA conditions and standards, and that a hearing is required to resolve that issue. Petitioner argues that its POC would have brought the laboratory into compliance, had the State Agency not caused what Petitioner calls the premature cessation

of its Medicare payments, resulting in "cash flow difficulties." P. RR at 7-8. Petitioner asserts that it received no Medicare or Medicaid payments since July 2005, prior to any determinations by CMS, and believes this resulted from actions of the State Agency. Id. at 4, 7-8.

Analysis

We find no merit to Petitioner's arguments on appeal. Those arguments, as previously noted, do not challenge the core of the ALJ Decision, that neither Petitioner's hearing request nor brief opposing CMS's motion disputed CMS's determination that Petitioner had four condition-level CLIA deficiencies at the time of the survey, a determination that authorized CMS to revoke Petitioner's provider agreement as a matter of law. Neither does Petitioner dispute the ALJ's legal conclusions that only the "initial determinations" listed in 42 C.F.R. § 493.1844(b) are subject to appeal and that the "initial determinations" listed do not include rejection of a POC.

Instead of challenging these core findings and conclusions, Petitioner argues that the rejection of its POC was the true basis of the sanctions that Petitioner challenges and was thus an appealable initial determination, even though not listed as such in the regulations. That argument is not supported by the CLIA appeal regulations which explicitly state, "Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal . . . ." 42 C.F.R. § 493.1844(c). Nor is it supported by the record in this case or other applicable regulations, which show that the bases of the sanctions that CMS imposed were Petitioner's undisputed condition-level deficiencies.[5]

[5] In its November 16, 2005, letter imposing sanctions, CMS referred to its earlier letter proposing sanctions, dated November 3, 2005, as follows: "By letter dated November 3, 2005, we proposed sanctions against HRT Laboratory Inc. as a result of the laboratory's failure to submit a credible allegation of compliance and acceptable evidence of correction for deficiencies cited at the March 8, 2005 survey of the laboratory." CMS Ex. 11, at 1. However, CMS's November 3 letter merely referred to the State Agency's recommendation that CMS initiate sanction action against HRT "[b]ased on the laboratory's repeated failure to provide a credible allegation of compliance and acceptable evidence of correction" and indicated CMS's concurrence in the recommendation. CMS Ex. 10, at 2. The section of the November 3

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The CLIA regulations make clear that it is a laboratory's noncompliance with CLIA requirements, including the requirement of successful participation in proficiency testing, that is the basis for a decision by CMS to impose sanctions. CMS's decision "is based on . . . (i) [d]eficiencies found by CMS or its agents in the conduct of inspections to certify or validate compliance with federal requirements," or "(ii) [u]nsuccessful participation in proficiency testing." 42 C.F.R. § 493.1804(b). CMS may impose principal and alternative sanctions "on a laboratory that is out of compliance with one or more CLIA conditions" (42 C.F.R. § 493.1806(a)) and may cancel the approval to receive Medicare payments of "laboratories that are out of compliance with one or more CLIA conditions" (42 C.F.R. § 493.1807(a)). The regulations also state that reviewable initial determinations include the "suspension, limitation, or revocation of the laboratory's CLIA certificate by CMS because of noncompliance with CLIA requirements." 42 C.F.R. § 493.1844(b)(1) (emphasis added).

Since the regulations authorize CMS to impose sanctions for noncompliance with CLIA requirements, an appeal of CLIA sanctions necessarily addresses whether a laboratory was in substantial compliance with CLIA requirements, and not whether corrective actions the laboratory proposed might have brought it into compliance. That the State afforded Petitioner an opportunity to submit a credible allegation of compliance and acceptable evidence of correction before recommending that CMS impose sanctions does not convert the State's and CMS's conclusions that Petitioner's submissions were not credible or acceptable into the basis for the sanctions. Thus, whether the corrective actions proposed by Petitioner might have brought Petitioner into compliance, as Petitioner asserts, is not material to whether the

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[5](...continued)
letter proposing sanctions clearly stated that the sanctions were being proposed "based on the laboratory's failure to meet four CLIA Conditions and the failure by the owners and the director of the laboratory to comply with certificate requirements and performance standards as evidenced by the findings from the March 8, 2005 survey." Id. at 12. CMS's November 16 letter imposing the sanctions used this identical language. Thus, there is no question that CMS imposed the sanctions (as it was authorized by law to do without giving an opportunity to correct) based on Petitioner's noncompliance with conditions of participation, not on the absence of a credible allegation of compliance or acceptable evidence of correction.

unchallenged condition-level deficiencies legally support CMS's determination to impose sanctions.[6]

Consistent with its authority under these provisions, CMS informed Petitioner that CMS was imposing sanctions based on Petitioner's failure to meet four CLIA conditions, and the failure by its owners and the director to comply with certificate requirements and performance standards, as evidenced by the State Agency's survey. CMS Ex. 11, at 1; see also CMS Ex. 10 (November 3, 2005 CMS letter to Petitioner concurring with the State Agency's noncompliance findings and proposing sanctions). Although CMS's November 3, 2005 letter explained why Petitioner's allegation of compliance was not credible and its evidence of correction was not acceptable, that does not mean that those findings, or the declination of Petitioner's POC, were bases for the imposition of sanctions. The CLIA regulations do not require CMS to afford a laboratory the opportunity to correct condition-level deficiencies (either through a POC or an allegation of compliance), for which CMS has imposed principal sanctions such as revocation. CMS was thus under no obligation to accept Petitioner's POC or to offer Petitioner additional time to correct the deficiencies before imposing sanctions.[7]

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[6] We also note that while the State Agency, as CMS's agent, may survey laboratories for CMS, give the laboratory notice of noncompliance and proposed sanctions and recommend sanctions to CMS, only CMS is authorized to impose sanctions. See, e.g., 42 C.F.R. § 493.1806 ("CMS may impose one or more of the sanctions specified . . . ."); 42 C.F.R. § 493.1810(c)("CMS gives the laboratory written notice . . . and specifies the following: (i) The sanction or sanctions to be imposed . . . ."). The State Agency made this clear to Petitioner in its notices. See CMS Ex. 9, at 10 (State Agency notice stating, "The CMS Regional Office has the final authority for any sanction actions to be imposed and will inform you of its determination and the appeals procedures.") Thus, to the extent Petitioner is relying for its arguments on the State Agency's role in rejecting the POCs as not credible or inadequately documented, that is irrelevant.

[7] If CMS has proposed alternative sanctions for condition-level deficiencies, it may allow up to 12 months for a laboratory to correct condition-level deficiencies that do not pose immediate jeopardy. 42 C.F.R. § 493.1814(b)(1). However, the option of affording this opportunity to correct condition-level deficiencies does not apply where, as here, CMS has also

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Thus, the basis of CMS's decision to impose sanctions was its determination that Petitioner had condition-level CLIA deficiencies. Petitioner here has not challenged CMS's noncompliance determinations, and no findings regarding Petitioner's proposed POC would alter those noncompliance determinations or remove CMS's basis for imposing sanctions.

Petitioner also argues that it is unaware of any patient being harmed by the deficiencies and that its laboratory poses no threat of future harm because it ceased operating in November 2005, and that the imposition of sanctions is inappropriately punitive. These arguments provide no basis to reverse the ALJ Decision. The applicable regulations authorize CMS to impose sanctions where, as here, there is noncompliance with a condition of participation; no showing of harm is required. See 42 C.F.R. § 493.2 (defining "[c]ondition level deficiency" without any reference to harm); see also Rustom Ali, Jahan Ferdous, and Scottsdale Medical Laboratory at 9 (showing of actual harm not required to find a violation of the requirement that a laboratory have adequate systems in place to report accurate results); Immuno Biogene, Inc., DAB No. 1946, at 23 (2004) (CMS does not have to prove that a given patient was harmed). Furthermore, one of Petitioner's four condition-level deficiencies was based on unsuccessful participation in proficiency testing. Petitioner does not deny that this unsuccessful participation might indicate that it reported inaccurate results of tests on patient specimens while it was in operation or that such inaccurate results posed

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proposed a principal sanction such as revocation. 42 C.F.R. §§ 493.1814(a)(3),(b)(1); accord Rustom Ali, Jahan Ferdous, and Scottsdale Medical Laboratory, DAB No. 2016, at 21-22 (2006), pet. denied, Ali v. U.S. Dept. of Health and Human Services, 2007 WL 2437809 (9th Cir. Aug. 23. 2007)(holding that the regulations under which CMS may afford an opportunity to correct "are inapposite" where CMS has proposed revocation). Where CMS gives a laboratory notice that CMS has identified condition-level noncompliance, it must allow at least 10 days for the laboratory to respond to the notice, during which time the laboratory may submit "written evidence or other information against the imposition of the proposed sanction or sanctions." 42 C.F.R. §§ 493.1810(a)(6),(b). CMS provided Petitioner that opportunity. CMS Ex. 10. However, this "is not a 'corrective period,' but rather means that the laboratory can avoid the proposed sanction(s) by providing information that causes CMS to conclude that the findings of noncompliance are wrong." Rustom Ali, Jahan Ferdous, and Scottsdale Medical Laboratory at 21-22.

at least the potential for harm to those patients. Finally, the Board has held that a laboratory's closing has no bearing on whether the laboratory had any condition-level deficiencies at the time it was surveyed, which remains relevant despite the closing, as no person who has owned or operated a laboratory which has had its CLIA certificate revoked may, within two years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued. Center Clinical Laboratory, DAB No. 1526, at 11 (1995), citing 42 U.S.C. § 263a(i)(3).

Conclusion

For the reasons discussed above, we uphold the ALJ Decision dismissing Petitioner's hearing request.

Judith A. Ballard

Leslie A. Sussan

Sheila Ann Hegy
Presiding Board Member